

EXHIBIT T

Declaration of Andrew Pack, Director of the West Virginia Bureau
of Medical Services' Office of Program Integrity

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION**

STATES OF TENNESSEE, ALABAMA,)
ARKANSAS, GEORGIA, IDAHO, INDIANA,)
IOWA, LOUISIANA, MONTANA,)
NEBRASKA, NORTH DAKOTA, OHIO,)
SOUTH CAROLINA, SOUTH DAKOTA, and)
WEST VIRGINIA,)

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND)
HUMAN SERVICES; XAVIER BECERRA, in)
his official capacity as Secretary of Health and)
Human Services; and U.S. DEPARTMENT OF)
HEALTH AND HUMAN SERVICES OFFICE)
OF CIVIL RIGHTS,)

Defendants.

Civil Action No. 25-cv-00025

DECLARATION OF ANDREW PACK

Pursuant to 28 U.S.C. § 1746, I, Andrew Pack, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.
2. I serve as Director of the West Virginia Bureau for Medical Services' Office of Program Integrity (OPI). OPI conducts post-payment reviews and is responsible for identifying fraud, waste, and abuse cases in West Virginia's Medicaid reimbursement system. OPI achieves this by completing the activities required under 42 C.F.R. § 456.
3. As part of my responsibilities, I regularly oversee audits of entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat.

1936 (1996) (HIPAA), seeking protected health information (PHI) to investigate Medicaid billing fraud, waste, and abuse.

4. Any credible allegations of fraud uncovered are referred to West Virginia's Medicaid Fraud Control Unit (MFCU). In turn, MFCU is authorized to continue investigating and issue subpoenas pursuant to West Virginia Code § 9-7-3(a) and 45 C.F.R. § 164.512, as MFCU performs both law enforcement and health oversight duties. Thus, in substantiated cases, OPI's investigations may lead to criminal charges brought by MFCU.

5. OPI routinely requests information from providers of services reimbursed by the West Virginia Medicaid program and health plan payers to investigate suspected Medicaid fraud. Given the nature of its investigations, OPI must request this information with imperfect knowledge of the possible misconduct being investigated because it is impossible to know the particulars of the investigation until OPI receives the information. Indeed, obtaining medical records and PHI is crucial to the investigation, reporting, and litigation of Medicaid fraud, waste, and abuse.

6. I have reviewed the Department of Health and Human Services' HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

7. The Final Rule creates compliance costs and barriers to investigation, impeding OPI's investigation of Medicaid fraud, waste, and abuse in West Virginia.

8. Before the Final Rule, OPI could request information without considering whether the information sought "potentially related" to "reproductive health care."

9. But under the Final Rule, if a covered entity receives a request for information from OPI and concludes that information even "*potentially* related" to "reproductive health care" is part

of the requested information, it may delay or withhold submission of the information requested until investigators provide an attestation that the information is not sought for a purpose prohibited by the Final Rule. *See* 45 C.F.R. § 164.509(a) (emphasis added). The Final Rule's prohibited purposes include using the information to "conduct a criminal, civil or administrative investigation" or to "impose criminal, civil, or administrative liability" on a person "seeking, obtaining, providing, or facilitating reproductive health care." *Id.* § 164.502(a)(5)(iii)(A).

10. And similarly, under the Final Rule, a covered entity that receives a request for PHI cannot disclose that information unless it "reasonably determine[s]" that the "reproductive health care" is either "lawful under the law of the state in which such health care is provided under the circumstances in which it is provided" or "protected, required, or authorized by Federal law, including the United State Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided." 45 C.F.R. § 164.502(a)(5)(iii)(B).

11. To make that assessment, the Final Rule instructs covered entities to presume that "reproductive health care" is lawful and therefore not subject to investigation by a State. 45 C.F.R. § 164.52(a)(5)(iii)(C). The only exceptions to this are if a covered entity has "[a]ctual knowledge that the reproductive health care was not lawful" or "[f]actual information supplied by the person requesting the use or disclosure of [PHI] that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.*

12. The covered entity receiving a request for PHI makes these determinations, and if it determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide recourse for the requesting entity.

13. Because of its new requirements, the Final Rule necessitates organization-level re-evaluation of OPI's systems and processes for requesting HIPAA-protected material. The need

for this evaluation is particularly justified by the risk of criminal liability that attaches to misusing HIPAA-protected information. 42 U.S.C. § 1320d-6(b).

14. OPI will be required to thoroughly consider the bases and potential ends of its investigations when requesting HIPAA-protected information from a covered entity with a particular focus on “reproductive health care.” Because of the Final Rule’s broad, vague standards, if there is any risk that “reproductive health care” information will be subsumed in the requested data, OPI will be required to seek consultation with legal counsel. And even once OPI is satisfied that it can provide an attestation, it must complete the form and provide it to the covered entity.

15. Indeed, OPI is particularly concerned that its investigators cannot truthfully fulfill the attestation requirement under the Final Rule because OPI cannot predict the ways information will be used if a case is later referred to MFCU. This is especially true considering the Final Rule’s expansive definition of “reproductive health care.”

16. In any case, the Final Rule places the power to assess the validity of an attestation entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information. This means that in some cases the entity under investigation will have a veto on OPI’s investigators’ ability to obtain records necessary for their investigation.

17. This process creates significant tangible costs, including time, resources and personal, that are likely to grow. But the costs do not end there: OPI’s investigations into important public health matters are necessarily slowed to undertake compliance with the Final Rule’s attestation requirements. Thus, in addition to imposing additional costs on OPI, the Final Rule is impacting the public health and safety of West Virginia by delaying, impeding, and deterring viable public health investigations.

Date: 4/2/25

A handwritten signature in blue ink, appearing to read "Andrew Pack", written over a horizontal line.

Andrew Pack

Director

Office of Program Integrity
